

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,

Plaintiff,

v.

AMERISOURCEBERGEN CORPORATION;
AMERISOURCEBERGEN DRUG
CORPORATION; and INTEGRATED
COMMERCIALIZATION SOLUTIONS, LLC,

Defendants.

Case No. 2:22-cv-05209-GJP

ORAL ARGUMENT REQUESTED

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS**

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INTRODUCTION

This lawsuit represents a glaring—and dangerous—example of governmental overreach, which exceeds the bounds of the Constitution, the applicable statutory framework, and the Federal Rules of Civil Procedure. AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and Integrated Commercialization Solutions, LLC (collectively, “Defendants”) distribute thousands of different medications, including controlled substances, to hospitals, pharmacies, and other healthcare providers around the country. FDA-approved prescription opioids are among the medications Defendants distribute. Defendants take the opioid crisis seriously. They have devoted extraordinary resources to combat diversion of controlled substances, including opioids, and have complied with all of the reporting requirements of the Controlled Substances Act (“CSA”). It is only by distorting those requirements that the Government can assert that Defendants violated the CSA.

The Complaint alleges that Defendants violated the CSA by failing to report to the Drug Enforcement Administration (“DEA”) “suspicious orders” of controlled substances that were placed by Defendants’ pharmacy and healthcare provider customers (including many military hospitals and other governmental entities). The Government alleges that Defendants committed “at least hundreds of thousands” of violations and seeks billions of dollars in penalties.

For a host of reasons, the Government’s lawsuit is profoundly flawed. First, the term “suspicious orders” is hopelessly vague and subjective, and therefore cannot be the basis for enforcement under recent Supreme Court jurisprudence. Indeed, this is an especially strong case for a vagueness argument, as the DEA is well aware that the suspicious order monitoring and reporting obligations are unclear and for years distributors like the Defendants have clamored for the DEA to provide clarifying guidance. Moreover, Congress and other parts of the federal government—including the United States Government Accountability Office (“GAO”) and the

Department of Justice’s own Office of the Inspector General (“OIG”)—have noted the confusion engendered by the suspicious order obligations and criticized the DEA for its failure to provide clarity. Yet, despite the DEA’s repeated promises, it has never provided the requisite clarity.

Worse yet, the Government is seeking to impose billions of dollars of penalties for Defendants’ alleged failure to submit reports that the DEA routinely ignored. In sworn Congressional testimony, the DEA has admitted that—for years—it mishandled the suspicious order reports it received and that it needed to make changes and actually “do something” with such reports. Following their own investigations, Congress and the GAO have blasted the DEA’s failure to act on suspicious order reports, with the Office of Inspector General noting that DEA field offices were unable even to locate the reports they had received.

Even more troubling, the Government’s claims relate to a time period (January 2014 to the present) beginning nearly two years *after* the Government began its languid investigation of Defendants. During these years, the DEA audited Defendants’ distribution centers dozens of times and never made any adverse findings regarding Defendants’ suspicious order monitoring and reporting systems. Moreover, the DEA renewed the registration for each of Defendants’ dozens of distribution centers every year during this period—a process which obligated the DEA to consider annually whether each facility was maintaining effective controls against diversion. *See* 21 U.S.C. §§ 822(a), 823(b). If the Government believed that Defendants’ systems violated the law, it could and should have raised issues during any of the DEA audits or as part of the annual registration process, or taken some other action against Defendants. It did not do so. Instead, it waited to bring suit until after Defendants and other distributors entered into a multibillion dollar settlement resolving thousands of civil lawsuits filed by state and local governments, and it now seeks to pile on by asking for unwarranted additional billions of dollars

in penalties for conduct occurring in years when Defendants passed every single audit, and the DEA approved the registration for every single one of Defendants' many distribution centers.

Lastly, the Government implicitly asks this Court to ignore, and reach a different conclusion than, the decision another federal court issued in the benchmark trial against distributors in the national opioid MDL. Defendant ABDC won that case on the merits following the conclusion of an extensive bench trial. In July 2022, the United States District Court for the Southern District of West Virginia ruled that ABDC's systems substantially complied with the Controlled Substances Act. In support of its ruling, the court issued a 184-page opinion following a bench trial in which 70 expert and lay witnesses testified (including current and former DEA officials). This opinion, the first and only ruling regarding the efficacy of Defendants' order monitoring systems, concluded that ABDC's order monitoring program was legally sufficient. That suit was filed by a city and county, in an area of West Virginia among the hardest hit by the opioid crisis, that accused ABDC (and other distributors) of failing to report suspicious orders and distributing an excessive volume of prescription opioids. In rejecting the plaintiffs' claims, the court rejected on the merits the very type of allegations that the Government raises here.

But the Complaint not only overreaches, it is legally flawed. It should be dismissed in its entirety for various compelling reasons:

First, it should be dismissed because it seeks to enforce obligations that are unconstitutionally vague. The Government seeks to recover billions of dollars in penalties based upon Defendants' alleged failure to report suspicious orders to the DEA. However, under United States Supreme Court precedent, the term "suspicious order" violates the Due Process Clause because it fails to inform distributors what is required of them and allows for arbitrary

enforcement. Moreover, the description of “suspicious order” in the operative statute and regulation provides no help because it relies upon terms that are themselves unconstitutionally vague. As noted, the vagueness of the reporting obligation is confirmed by the numerous requests for guidance by distributors; the repeated criticisms of the DEA and calls for clarity by Congress and other governmental entities; and by the DEA’s continuing steadfast refusal to answer Defendants’ explicit inquiries or provide any meaningful guidance whatsoever. The DEA’s failure to provide clarity has left distributors unsure about how to comply with their obligation to report suspicious orders and negatively impacted patient access to needed medications.¹ Under the circumstances, it is difficult to understand how this statutory scheme could be other than unconstitutionally vague.

Second, the Complaint should be dismissed because the alleged reporting violations are all premised on a fundamental misreading of the statute and regulations. Distributors are obligated to design and operate a system to identify suspicious orders and then report to the DEA the suspicious orders so discovered. The Government’s own Complaint does not dispute that Defendants designed and operated such systems. Instead, ten years after the fact, the Government now alleges hundreds of thousands of reporting violations based on alleged deficiencies in Defendants’ systems. In fact, a significant portion of the Government’s allegations concerns orders that were never flagged by Defendants’ order monitoring programs for further review, much less determined to be suspicious. But the Government cannot base a violation on an alleged failure to discover that an order is suspicious—only on the failure to

¹ The *New York Times* recently published an article noting that the vagueness of the suspicious order reporting obligations has led to patient access problems. See Christina Jewett & Ellen Gabler, *Opioid Settlement Hinders Patient Access to a Wide Array of Drugs*, NEW YORK TIMES (Mar. 13, 2023), <https://www.nytimes.com/2023/03/13/us/drug-limits-adhd-depression.html>.

report an order actually discovered to be so. The Complaint also violates Federal Rule of Civil Procedure 8 because it fails to identify the specific orders covered by its sweeping allegations.

Third, the Complaint separately fails to state a claim with respect to Defendants' alleged violations prior to October 24, 2018, when Congress enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities ("SUPPORT") Act, P.L. 115-273. In its Complaint, the Government seeks penalties under a provision of the CSA that prohibits the failure to make any report that is required "under this subchapter." 21 U.S.C. § 842(a)(5). Supreme Court and Third Circuit precedent interpret the term "this subchapter" to apply only to the applicable statute itself, and not to regulations. Until the enactment of the SUPPORT Act, however, no provision of the CSA itself obligated distributors to report suspicious orders to the DEA. Instead, the suspicious order reporting obligation appeared solely in a DEA regulation. Accordingly, the Government's pre-SUPPORT Act allegations fail.

Fourth, the pre-SUPPORT Act allegations should also be dismissed in light of the DEA's failure to comply with the Paperwork Reduction Act ("PRA"). The PRA provides that no person may be penalized for failing to comply with a regulatory request for information unless the agency has first obtained approval under the PRA to collect that information. Here, with respect to the pre-SUPPORT Act time period, the Government seeks massive penalties based solely upon Defendants' alleged failure to collect and provide information—reports of suspicious orders—under a DEA regulation for which the DEA still has never obtained PRA approval. The DEA's failure to obtain such approval provides Defendants with a "complete defense" to liability. 44 U.S.C. § 3512(b).

BACKGROUND

I. THE PARTIES

Plaintiff is the United States of America (the “Government”). Compl. ¶ 13. Defendant AmerisourceBergen Corporation (“AB”) is a pharmaceutical distribution company. *Id.* ¶ 63. Defendants AmerisourceBergen Drug Corporation (“ABDC”) and Integrated Commercialization Solutions LLC (“ICS”) are subsidiaries of AB that distribute thousands of medications, including controlled substances, to pharmacies, hospitals, and other entities (including federal military facilities) through DEA-registered distribution centers. *Id.* ¶¶ 17, 66-72, 77-78. The distribution of prescription opioids comprises less than 2% of AB’s annual revenue.²

II. THE CSA AND REGULATORY FRAMEWORK

“Controlled substances” are drugs that appear on any of five controlled substance schedules created by the CSA. 21 U.S.C. § 802(6). The CSA establishes “a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the [Act].” *Gonzales v. Raich*, 545 U.S. 1, 13 (2005); *see generally* Compl. ¶¶ 33-36, 44. “Under the closed system, DEA-registered manufacturers may sell controlled substances only to DEA-registered distributors and pharmacies; DEA-registered distributors may distribute controlled substances only to DEA-registered dispensers (such as pharmacies and hospitals); and DEA-registered dispensers may dispense controlled substances only pursuant to prescriptions written by DEA-registered prescribers.” *City of Huntington v. AmerisourceBergen Drug Corp.*, 609 F. Supp. 3d 408, 421 (S.D. W.Va. 2022); *see also* Compl. ¶ 34.

² AB Proxy Statement (Jan. 28, 2021) at 8, available at https://www.sec.gov/Archives/edgar/data/1140859/000110465921008422/tm2039342-1_def14a.htm.

A. The DEA Registration Process

Every participant in the closed system must be registered by the DEA. Compl. ¶ 35.

Distributors must obtain a DEA registration annually for each of their distribution facilities. 21 U.S.C. §§ 822(a)(1), 822(e)(1). The DEA may deny registration if it “determines that such registration is inconsistent with the public interest.” *Id.* § 823(a). To make this “public interest” assessment, the CSA directs the DEA to consider certain factors, including whether the distributor maintains “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” *Id.* § 823(b)(1); *see* Compl. ¶ 40.

Neither the CSA nor the implementing regulations define “effective controls.” The DEA uses “the security requirements set forth in §§ 1301.72 – 1301.76 [of its regulations] as standards for the physical security controls and operating procedures necessary to prevent diversion.” 21 C.F.R. § 1301.71(a). While these requirements largely address physical handling and security of controlled substances (*e.g.*, specifications for storage areas, vaults, alarms), one provision, 21 C.F.R. § 1301.74(b) (the “SOR Regulation”), requires suspicious order monitoring and reporting.

The SOR Regulation obligates a registrant (i) to “design and operate a system to disclose to the registrant suspicious orders of controlled substances,” and (ii) to notify the DEA of such orders “when discovered by the registrant.” *Id.*; Compl. ¶ 47. The system required by the SOR Regulation is often referred to as a suspicious order monitoring system (“SOMS”) or an order monitoring program (“OMP”). The SOR Regulation defines suspicious orders to “include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b). These terms, however, are undefined, and the DEA has refused to clarify their meaning or application. *See infra* 9-15. Nor has the DEA provided guidance on how to design or operate a SOMS. *Id.* Instead, the DEA has stated that “it is the

sole responsibility of the registrant to design and operate” a SOMS and that the “DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.” *E.g.*, Joseph T. Rannazzisi, DEA, Letter to Registrants (Dec. 27, 2007) (attached as Ex. 1); *see also* Compl. ¶ 97 (referring to letter).³

The DEA may revoke a registration if a distributor “commit[s] such acts” making its continued registration “inconsistent with the public interest.” 21 U.S.C. § 824(a)(4). In order to ascertain whether that is so, the DEA conducts cyclical compliance inspections. *Id.* § 822(f). DEA’s inspections include, among other things, reviewing a distributor’s policies and procedures for maintaining effective controls against diversion and its customer due diligence files. *Huntington*, 609 F. Supp. 3d at 422. In addition, distributors must report, at least quarterly, controlled substance transactions to a DEA database called ARCOS. 21 U.S.C. § 827(d)(1); 21 C.F.R. § 1304.33(c). The DEA conducted dozens of audits of Defendants and received their ARCOS reporting, and at no time did the DEA make any adverse findings regarding Defendants’ systems.

³ A court ruling on a motion to dismiss may consider a “document integral to or explicitly relied upon in the complaint.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotations omitted). The Court also may consider “matters of public record” on a motion to dismiss, including “published reports of administrative bodies” and an agency’s submissions to Office of Management and Budget (“OMB”) under the PRA. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d Cir. 1993); *E.B. v. U.S. Dep’t of State*, 583 F. Supp. 3d 58, 64 n.7 (D.D.C. 2022) (citing agency’s submission to OMB concerning proposed collection of information); *Nat'l Urb. League v. Ross*, 508 F. Supp. 3d 663, 678 n.2 (N.D. Cal. 2020) (taking judicial notice of GAO reports); *United States ex rel. Woodard v. DaVita, Inc.*, No. 1:05-CV-227, 2011 WL 13196556, at *6 n.6 (E.D. Tex. May 9, 2011) (taking judicial notice of OIG reports); *Valiente v. Dineequity, Inc.*, No. CIV.A. 08-2416-KHV, 2009 WL 1226743, at *1 (D. Kan. May 1, 2009) (“Courts often take judicial notice of various public records, including legislative committee reports . . .”).

B. The SUPPORT Act

In October 2018, Congress passed the SUPPORT Act, which for the first time added to the CSA itself a suspicious order reporting requirement that largely mirrors the requirement found in the SOR Regulation. 21 U.S.C. § 832(a); Compl. ¶ 51. While the contours of the suspicious order reporting requirement did not change, the implications for non-compliance did: Congress has authorized civil and criminal penalties for violations of a reporting requirement listed in Subchapter I of the CSA. *See* 21 U.S.C. §§ 842(a)(5), 842(c)(1)-(2). However, prior to the SUPPORT Act, Subchapter I did not include a suspicious order reporting requirement and, therefore, the statutory scheme did not authorize penalties for violations of the SOR Regulation. Rather, any such violations were relevant only to the registration process.

III. DEA'S REFUSAL TO PROVIDE SUSPICIOUS ORDER GUIDANCE

The DEA has long evaded repeated calls from Congress, other parts of the Government, the industry, and Defendants to clarify the vague suspicious order framework. At the same time, governmental authorities have found that the DEA rarely uses the suspicious order reports it receives, and that the DEA's failure to provide guidance both unfairly left distributors unsure about how to comply with their obligations and could negatively impact patient access to medications. For example:

June 2015 GAO Report: In response to industry feedback, including criticism that the DEA failed to provide "a clear road-map for what is expected to be compliant" with the SOR Regulation, the GAO recommended that the DEA "develop additional guidance for distributors regarding their roles and responsibilities for suspicious order monitoring and reporting."⁴ GAO

⁴ U.S. Gov't Accountability Off., GAO-15-471, *Prescription Drugs: More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help*

warned that “without sufficient guidance and communication from DEA, distributors may not be fully understanding or meeting their roles and responsibilities under the CSA” June 2015 GAO Report at 27. The DEA dismissed GAO’s recommendations, stating that “[s]hort of providing arbitrary thresholds to distributors, DEA cannot provide more specific suspicious orders guidance, as the variables that indicate an order is suspicious are very fact intensive and differ from distributor to distributor, and from customer to customer.” *Id.* at 45. But GAO disagreed with the DEA. It noted that the “[DEA] was able to create such guidance for pharmacy and practitioner registrants” and that it “continue[d] to believe that DEA could provide additional written guidance for distributors.” *Id.* at 45-46.

June 2016 GAO Congressional Testimony: In Congressional testimony a year later, GAO’s Director of Homeland Security and Justice reiterated the need for the DEA to “provide a guidance document for distributors” including “best practices in developing suspicious order monitoring systems.”⁵ GAO expressed concerns that “[i]n the absence of clear guidance from DEA, our survey data show that many distributors are setting thresholds on the amount of certain controlled substances that can be ordered by their customers . . . , which can negatively impact pharmacies and ultimately patients’ access.” June 2016 GAO Testimony at 19.

March 2018 DEA Congressional Testimony: In the wake of widespread DEA breakdowns, the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce convened a hearing on the DEA’s role in combatting the opioid

Ensure Access 26, 44 (June 2015) (“June 2015 GAO Report”), available at <https://www.gao.gov/assets/gao-15-471.pdf>.

⁵ *Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations*, Statement of Diana C. Maurer, Director, Homeland Security and Justice, GAO 17 (June 22, 2016) (“June 2016 GAO Testimony”), available at <https://www.gao.gov/assets/gao-16-737t.pdf>.

epidemic.⁶ Members of the Committee blasted the DEA for “stonewall[ing]” and noted that it had been a “battle to get information out of the DEA.” 3/20/18 E&C Hearing Tr. at 3, 36. When asked about suspicious order reports, the DEA’s then-Acting Administrator admitted to “structural problems” and said that the DEA was making changes because “we have to do something with [suspicious order reports] when we get them.” *Id.* at 64. He further testified that the DEA was “in the final stretch” on a new SOR regulation. *Id.* at 42. But, as discussed below, that new regulation was not proposed until two and a half years later, and it failed to provide any additional guidance regarding the meaning of a suspicious order.

September 2019 OIG Report: In a report criticizing the DEA’s diversion control efforts, OIG observed that “registrants seemingly are applying varying standards and thresholds regarding unusual ordering behavior.”⁷ OIG joined the mounting calls for the DEA to “establish regulations, policies, and procedures that specifically define what constitutes a suspicious order, as well as what information should be included in a suspicious order report.” September 2019 OIG Report at 32. The OIG report further noted that field division staff at multiple sites throughout the country were unable to locate suspicious order reports that had been sent to them. *Id.* at 30-31.

January 2020 GAO Report: In a report entitled “Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders,” the GAO found that suspicious order

⁶ The DEA’s Role in Combating the Opioid Epidemic: Hearing Before the House of Reps. Subcommittee on Oversight and Investigations Committee on Energy and Commerce, 115 Cong. 110 (2018) (“3/20/18 E&C Hearing Tr.”), available at <https://www.govinfo.gov/content/pkg/CHRG-115hhrg30665/pdf/CHRG-115hhrg30665.pdf>.

⁷ U.S. Dep’t of Justice, Off. of Inspector Gen., Evaluation and Inspections Division 19-05, *Review of the DEA’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids* at 31 (Sept. 2019) (“September 2019 OIG Report”), available at <https://oig.justice.gov/reports/2019/e1905.pdf>.

monitoring and reporting methods vary widely, that such reports have limited utility, and that the DEA “rarely use[s] suspicious order reports to generate potential investigative leads.”⁸ GAO again concluded that “additional guidance from and additional communication with DEA was needed about registrants’ roles and responsibilities under the CSA.” *Id.* at 34-35.

The DEA took no action to address these problems until November 2020, more than five years after GAO’s initial call to action, when the agency proposed its first ever substantive revision to the SOR Regulation.⁹ Yet, the proposed rule still offers no standards for designing or operating a SOMS. Nor does it shed any light on what constitutes a suspicious order. Instead, the proposed rule is largely process-based.

Specifically, the DEA proposes to introduce a brand new, also-hopelessly-vague term, Orders Received Under Suspicious Circumstances (“ORUSC”), which DEA defines as “an order *potentially* meeting the definition of suspicious order.” *Id.* at 69,298 (emphasis added). The proposed rule states: “[u]pon receipt of an ORUSC, [distributors] will have a choice . . . to either: (1) immediately file a suspicious order report . . . , decline to distribute [the order], and maintain a record of the suspicious order and any due diligence related to [it], or (2) before distributing pursuant to the order, conduct due diligence to investigate each suspicious circumstance surrounding the ORUSC, and maintain a record of [such diligence].” *Id.* at 69,283. Under the second option, “if, through its due diligence, the registrant is able to dispel each suspicious circumstance . . . , it is not a suspicious order.” *Id.*

⁸ U.S. Gov’t Accountability Off., GAO-20-118, *Drug Control: Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders* 32-34 (Jan. 2020) (“January 2020 GAO Report”), available at <https://www.gao.gov/assets/gao-20-118.pdf>.

⁹ Notice of Proposed Rulemaking, *Suspicious Orders of Controlled Substances*, 85 Fed. Reg. 69,282 (Nov. 2, 2020) (the “SOR Notice”), available at <https://bit.ly/3EFD0QW>.

The SOR Notice makes clear that the proposed rule would impose “new requirements” for “recordkeeping.” *Id.* at 69,291. Thus, the DEA sought OMB approval under the Paperwork Reduction Act for this “new collection of information.”¹⁰ It explained that (1) the “[c]ollection would include two distinct components: the reporting of suspicious orders, and recordkeeping related to suspicious orders and ORUSCs,” and (2) because “[t]his is a *new information collection* . . . there is not a previous burden to compare it to.”¹¹ The DEA estimated that each year, the industry would receive approximately 339,000 orders under either category, but that only 20% (approximately 67,000 for all distributors combined) would be reported as suspicious. DEA Supp. Stmt., Ex. 2 at 3. It estimated distributors would spend 15 minutes per order complying with the new requirements, except when suspicious order reports were made, which would add five minutes to the process. *See id.*

On March 29, 2021, OMB notified the DEA that it was “withholding approval of this information collection,” and directed the DEA to provide OMB with a summary of comments it received regarding the new document collection burden.¹² The comment period closed in March 2021, yet to date, the DEA has not taken any further action with respect to the proposed rule. OMB now describes the status of the SOR Notice as “[h]istorical inactive.”¹³

¹⁰ DEA Supp. Stmt. for Paperwork Reduction Act Submissions, Suspicious Orders of Controlled Substances at 1 (submitted Dec. 8, 2020) (“DEA Supp. Stmt.”), available at <https://bit.ly/3IwuLI7> (attached as Ex. 2).

¹¹ Off. of Mgmt. & Budget, View Information Collection Request (ICR) Package, ICR Ref. No. 202012-1117-001 (Received Dec. 8, 2020) (emphasis added), available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202012-1117-001#section2_anchor (attached as Ex. 3).

¹² Notice of Office of Management and Budget Action, ICR Ref. No. 202012-1117-001 (Mar. 29, 2021) (attached as Ex. 4).

¹³ View Information Collection Request (ICR) Package, ICR Ref. No. 202012-1117-001 (Ex. 3).

Meanwhile, GAO continues to press the DEA to implement its June 2015 recommendations. In a June 2, 2022 letter to Attorney General Merrick Garland identifying “high priority” open recommendations, GAO reiterated the need for clear SOR guidance:

Recommendation: . . . [T]he Deputy Assistant Administrator for the Office of Diversion Control should solicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious orders monitoring and reporting.¹⁴

GAO further noted that such guidance would “help[] registrants make business decisions that balance ensuring access for patients with legitimate needs with controlling abuse and diversion.”

Id.

At the same time, members of Congress also continue to press for action. A proposed bill in the House of Representatives would require the Attorney General to “promulgate a final regulation specifying the indicators that give rise to a suspicion that, if an order or series of orders is filled, the drugs that are the subject of the order or series of orders are likely to be diverted.”¹⁵

Yet, as recently as January 20, 2023, the DEA still refuses to provide guidance about how a SOMS should be designed or implemented. When asked whether the CSA or DEA regulations require distributors to impose quantitative limits “on the amounts of controlled substances . . . that another DEA registrant can order or dispense,” the DEA responded: “No.”¹⁶ It explained:

¹⁴ June 2, 2022 Letter from Gene Dodaro, Comptroller General of the United States, to The Hon. Merrick B. Garland at 5 (“June 2022 GAO Letter”), available at <https://www.gao.gov/assets/gao-22-105703.pdf> (attached as Ex. 5).

¹⁵ Block, Report and Suspend Suspicious Shipments Act of 2023, H.R. 501, 118th Cong. (2023), available at <https://www.congress.gov/bill/118th-congress/house-bill/501/text>.

¹⁶ DEA-DC-065, *DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders* (Jan. 20, 2023), available at [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-065\)\(EO-DEA258\) Q_A SOR and Thresholds \(Final\).pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258) Q_A SOR and Thresholds (Final).pdf).

[M]any DEA-registered . . . distributors establish controlled substance monitoring systems that set thresholds that may limit the amount of a customer’s controlled substance purchases and may prompt a report of a suspicious order to DEA. However, whether to set such thresholds (if any) and at what levels are decisions that each manufacturer or distributor may make in the design and implementation of its controlled substance monitoring system. DEA does not have a role in establishing or revising thresholds for controlled substances that manufacturers or distributors may set for their customers as part of the required monitoring systems.¹⁷

IV. DEFENDANTS’ DIVERSION CONTROL PROGRAM

Against this backdrop of uncertainty, Defendants have designed, implemented, and continuously striven to improve their diversion control program—a program that dates back to the 1990s. The program includes (i) a “Know Your Customer” component for approving customers that involves obtaining and analyzing information designed to identify “red flags” indicating that a potential customer might be engaged in diversion (Compl. ¶¶ 89-90, 102, 118-122); (ii) daily order monitoring to identify and report suspicious orders (*id.* ¶¶ 102, 150, 197); (iii) ongoing due diligence of existing customers, which can include obtaining and reviewing dispensing data and sending outside auditors to conduct site visits when appropriate (*id.* ¶¶ 124-125); and (iv) terminating controlled substances sales to customers for diversion control reasons and reporting such terminations to the DEA. *Id.* ¶¶ 91-94. The program is summarized in written policies and procedures (*id.* ¶¶ 102, 213, 215, 217, 253, 259), and carried out by and under the direction of a dedicated compliance team headed by former DEA agents (*id.* ¶¶ 18, 88-95, 106).

As the Government recounts, Defendants’ order monitoring programs have been continually updated over time. In 2007, ABDC implemented a new OMP using computer algorithms based on “customer peer groups” to flag and hold certain orders of interest.

¹⁷ *Id.*

Defendant personnel then reviewed these orders of interest to determine whether they were suspicious. *Id.* ¶¶ 152-55, 213. Then, in 2014, AB hired experienced outside consultants to assist in developing an updated OMP. *Id.* ¶¶ 169, 171, 175. Like the predecessor system, the revised OMP utilized a two-step framework to determine whether an order was suspicious. At the first step, it used computer algorithms to flag orders of interest based on a comparison to a peer group of customers as well as the customer's own ordering history. *Id.* ¶¶ 181-84. Human reviewers then adjudicated those orders to determine whether they were suspicious. *Id.* ¶¶ 213, 215-17.¹⁸

Despite the Government's claims that Defendants' evolving systems were deficiently designed and/or implemented, the Government does not—and cannot—allege that the DEA suspended, revoked, or denied registration to any of Defendants' distribution centers during the period covered by the Complaint. Likewise, despite the DEA regularly inspecting Defendants' 25+ distribution centers and suspicious order monitoring programs throughout the relevant period, there is not a single allegation that the DEA ever issued an adverse finding regarding Defendants' order monitoring programs or that it recommended any changes whatsoever to those programs over the past decade.

V. ABDC'S WEST VIRGINIA VICTORY

On July 4, 2022, following a ten-week bench trial, the United States District Court for the Southern District of West Virginia ruled that ABDC's systems complied with the CSA. *Huntington*, 609 F. Supp.3d at 425. The plaintiffs in that case, a city and county in West

¹⁸ Although the Government criticizes aspects of the revised OMP, including what it refers to as the “dual trigger” requirement (*id.* ¶ 185), AB transparently presented and disclosed the workings of its program to the Government (including the so-called “dual trigger”) when it was being updated and during numerous audits since that time. In fact, AB gave the Government a 25-page briefing book describing the program more than six years ago which appears to form the basis for certain of the Government's allegations.

Virginia, claimed that ABDC and two other distributors caused the opioid epidemic in West Virginia by failing to block and report suspicious orders. *Id.* at 413, 438, 476.

In its 184-page opinion, the Court examined ABDC’s order monitoring program from 1998 through 2022, noting that ABDC’s “Suspicious Order Monitoring Program has evolved and changed over the years.” *Id.* at 425. After hearing testimony from 70 expert and lay witnesses (including current and former DEA officials), the Court concluded that ABDC “had in place suspicious order monitoring (‘SOM’) systems as required by the CSA and its implementing regulations.” *Id.* Further, the Court held that ABDC “substantially complied with [its] duties under the CSA to design and operate a SOM system and report suspicious orders.” *Id.*; *see id.* at 476 (“At all relevant times, defendants’ SOM systems were designed to identify suspicious orders.”). Notably, the Court recognized that if distributors improperly report too many orders as suspicious, there would “inevitably [be] supply problems for patients with legitimate needs for controlled substances.” *Id.* at 480.

VI. SUMMARY OF THE GOVERNMENT’S ALLEGATIONS

Notwithstanding that ABDC’s suspicious order monitoring systems were found to be compliant in the only trial addressing its SOMS, and that AB has already entered into a global settlement with state and local governments agreeing to pay up to approximately \$6.4 billion for those governments to use to mitigate the effects of the opioid epidemic,¹⁹ the Government has decided to pile on after a meandering ten-year investigation. In its Complaint, the Government asserts a single cause of action for penalties under 21 U.S.C. § 842(a)(5), a provision that makes it unlawful “to refuse or negligently fail to make . . . any report . . . required under this

¹⁹ See AB Form 10-K (Nov. 22, 2022) at 19, available at <https://www.sec.gov/ix?doc=/Archives/edgar/data/1140859/000114085922000098/abc-20220930.htm>.

subchapter” Compl. ¶¶ 503-06. The Government alleges that from January 1, 2014 to present, Defendants refused or negligently failed to report suspicious orders to the DEA. *E.g.*, Compl. ¶¶ 80, 443, 503-06. Yet, despite seeking billions of dollars in penalties, and conducting a decade-long investigation, the Government fails to say which of the “tens of millions of orders” that Defendants fill each year (*id.* ¶ 74) were allegedly suspicious, much less explain why each such order was allegedly suspicious and how Defendants were allegedly negligent in failing to report each order.

As discussed below, the Government fails to state a claim for various reasons. First, the Complaint fails in its entirety because it is based upon Defendants’ purported violation of suspicious order reporting obligations that are unconstitutionally vague. Second, the Government’s claims fail under the express terms of the SOR Regulation and SUPPORT Act, and violate Federal Rule of Civil Procedure 8, to the extent they are based upon allegations that Defendants failed to report orders that their own systems did not discover to be suspicious. And third, the Government’s allegations are legally deficient to the extent they are based upon conduct occurring pre-SUPPORT Act because the CSA did not at that time authorize penalties for not reporting suspicious orders and, further, because the DEA never obtained Paper Reduction Act approval to impose this reporting requirement in the first place.

ARGUMENT

I. THE “SUSPICIOUS ORDER” OBLIGATIONS ARE UNCONSTITUTIONALLY VAGUE.

The Government seeks billions of dollars in civil penalties based upon Defendants’ alleged failure to report suspicious orders to the DEA. The foundation for the Government’s Complaint is the SOR Regulation and the SUPPORT Act, both of which obligate distributors to design and operate a system to identify suspicious orders and to notify the DEA of such orders if

and when discovered. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 832(a) (cited in Compl. ¶¶ 47, 51, 504-505). Under these provisions, a “suspicious order” is vaguely and circularly defined to include orders of “unusual size,” orders that deviate “substantially” from a “normal pattern,” and orders of “unusual frequency.” 21 C.F.R. § 1301.74(b); 21 U.S.C. § 802(57). Despite repeated calls by Congress, various governmental entities, and distributors for the DEA to define with clarity distributors’ legal obligations, the DEA has never provided meaningful guidance regarding how distributors should design and operate an order monitoring system, and it has refused to define any of the terms “unusual size,” “substantially,” “normal pattern,” and “unusual frequency,” though these general terms certainly warrant further definition.

Without such guidance, the obligation to report “suspicious orders” is unconstitutionally vague and an impermissible basis for the billions of dollars in penalties that the Government seeks here. The definition of a “suspicious order” means different things to different people—a position the DEA has repeatedly conceded and even embraced. As such, even distributors that are trying their hardest to comply may get caught in the Government’s web. Moreover, two different distributors may receive different regulatory treatment with respect to their handling of virtually identical orders. Worse yet, the vagueness of these standards allows the DEA to change its interpretation of what conduct constitutes a violation without notice based upon the politics of the moment. Because the Constitution does not allow the Government to impose massive penalties based upon such amorphous, shifting, and ill-defined standards, the Complaint should be dismissed.

A. To Satisfy the Due Process Clause, Obligations Must Be Definite and Clear.

The Due Process Clause requires clarity in statutes and regulations. If a statute is not sufficiently clear, then it is invalid under the “void for vagueness” doctrine. This doctrine “addresses at least two connected but discrete due process concerns: first, that regulated parties

should know what is required of them so they may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way.” *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253-54 (2012). The doctrine is a “corollary of the separation of powers—requiring that Congress, rather than the executive or judicial branch, define what conduct is sanctionable and what is not.” *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018); *see also United States v. Davis*, 139 S. Ct. 2319, 2323-24 (2019) (vague laws improperly “hand off the legislature’s responsibility”). The Supreme Court has explained that the doctrine furthers “the ‘first essential of due process law’,” *i.e.*, “that statutes must give people ‘of common intelligence’ fair notice of what the law demands of them.” *Davis*, 139 S. Ct. at 2325 (quoting *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926)). When a statute is vague, courts are not free to rewrite it, but must “treat the law as a nullity and invite Congress to try again.” *Id.* at 2323.

The void for vagueness doctrine applies to both civil and criminal statutes. *Boutilier v. INS*, 387 U.S. 118, 123 (1967); *Dimaya*, 138 S Ct. at 1228 (Gorsuch, J., concurring). While lesser degrees of specificity may be required for civil than criminal statutes in certain contexts, the degree of specificity that is required turns on the severity of the consequences for non-compliance, not on the “label” that is attached to the statute. *Giaccio v. Pennsylvania*, 382 U.S. 399, 402 (1966). Here, the Government seeks billions of dollars in penalties. Accordingly, the same standard that is applied to criminal laws applies here. *See, e.g., Mateo v. Attorney General United States*, 870 F.3d 228, 232 (3d Cir. 2017) (“[B]ecause the consequences of deportation are likewise severe, we take this opportunity to clarify that the vagueness doctrine should be applied in the civil immigration context just as it is applied in the criminal context”); *see also Dimaya*, 138 S. Ct. at 1229 (“[I]f the severity of the consequence counts when deciding the standard of

review, shouldn’t we also take account of the fact that today’s civil laws regularly impose penalties far more severe than those found in many criminal statutes?”) (Gorsuch, J., concurring).

B. The Supreme Court Has Reinvigorated the Void for Vagueness Doctrine.

Over the last decade, the Supreme Court has reinvigorated the void for vagueness doctrine. On three separate occasions, it has struck down statutes, in both the criminal and civil contexts, for failing to satisfy the constitutional requirement of clarity. *See Johnson v. United States*, 576 U.S. 591 (2015); *Dimaya*, 138 S. Ct. 1204; *United States v. Davis*, 139 S. Ct. 2319 (2019). In *Dimaya*, for instance, the Court struck down a deportation statute that turned on whether the petitioner had committed a “crime of violence,” a term that was defined to include any felony that “by its nature, involves a substantial risk that physical force . . . may be used in the course of committing the offense.” 18 U.S.C. § 16(b). The Court explained that, “[b]y combining indeterminacy about how to measure the risk posed by a crime with indeterminacy about how much risk it takes for the crime to qualify as a violent felony,” the statute violated the Constitution. *Dimaya*, 138 S. Ct. at 1214.

Moreover, and significantly, the Court’s recent precedent makes clear that a vague law will not pass constitutional muster just “because there is some conduct that clearly falls within the provision’s grasp.” *Johnson*, 576 U.S. at 602. Looking to its prior holdings, the Court explained that “we have deemed a law prohibiting grocers from charging an ‘unjust or unreasonable rate’ void for vagueness—even though charging someone a thousand dollars for a pound of sugar would surely be unjust and unreasonable.” *Id.* (citing *United States v. L. Cohen Grocery Co.*, 255 U.S. 81 (1921)). Likewise, the Court struck down a statute prohibiting engaging in “annoying” conduct while on a public sidewalk, even though “spitting in someone’s face would surely be annoying.” *Id.* (citing *Coates v. Cincinnati*, 402 U.S. 611 (1971)). Thus,

even if a law unambiguously applies to some conduct, it may still be unconstitutionally vague. *Id.* at 603.

In its recent cases, the Supreme Court has relied upon two older cases that struck down statutes that purported to regulate business activity: *Connally v. General Construction Co.*, 269 U.S. 385 (1926), and *United States v. L. Cohen Grocery Co.*, 255 U.S. 81 (1921). In *Connally*, the statute obligated certain employers to pay wages that were “not less than the current rate of per diem wages in the locality where the work is performed.” 269 U.S. at 388. The Supreme Court held that the statute was unconstitutionally vague, explaining that the statute suffered from two separate infirmities: First, the “words ‘current rate of wages’ do not denote a specific or definite sum,” including whether the required wages must be higher than the maximum, minimum, or some other measure of the wages paid in the locality. *Id.* at 393. Second, “additional obscurity [was] imparted to the statute by the use of the qualifying word ‘locality.’ Who can say, with any degree of accuracy, what areas constitute the locality where a given piece of work is being done?” *Id.* at 394. Accordingly, because the “application of the law depend[ed], not upon a word of fixed meaning in itself, or one made definite by statutory or judicial definition, or by the context or other legitimate aid to its construction,” the statute violated the “constitutional guaranty of due process.” *Id.* at 395; *see also Johnson*, 576 U.S. at 596; *Sessions*, 138 S. Ct. at 1212; *Davis*, 139 S. Ct. at 2325 (all citing *Connally* with approval). Similarly, in *Cohen*, a law prohibited grocers from willfully charging any “unjust or unreasonable rate or charge.” 255 U.S. at 86. The Court held that the law was unconstitutional because it “forbids no specific or definite act” and, instead, “leaves open . . . the widest conceivable inquiry,” the result of which no one can “adequately guard against.” *Id.* at 89; *see also Johnson*, 576 U.S. at 598, 602-03; *Davis*, 139 S. Ct. at 2325 (citing *Cohen* with approval).

C. The Term “Suspicious Order” is Unconstitutionally Vague.

Here, the term “suspicious order” is unconstitutionally vague and imprecise. Just like the terms “locality” (*Connally*), or “unjust or unreasonable” (*Cohen*), the meaning of the term “suspicious” is in the eye of the beholder. Is an order “suspicious” because it is one pill larger than a pharmacy’s average order? Because it is twice as large as a pharmacy’s average order? How about three times? Is an order suspicious because a pharmacy typically makes 10 orders per month, but in one month it made 12 orders? 15 orders? Does it matter if the pharmacy orders the same amount of medication in its 15 orders that it typically orders in its 10 orders? These and myriad other questions are left unresolved by the language of the statute, unfairly leaving distributors at risk of exorbitant penalties based upon their inability accurately to read the DEA’s mind.

Moreover, defining the term “suspicious order” through the use of other, imprecise terms—such as “unusual size,” “substantial[]” deviation from a “normal pattern,” and “unusual frequency”—does nothing to help because those other terms are themselves elastic and rife for arbitrary enforcement. For example, when determining what constitutes a “normal pattern” of ordering for a particular pharmacy, should the distributor look at the pharmacy’s own purchasing history, or the purchasing history of other pharmacies? If the former, should the distributor look to the last six months’ worth of orders, last 12 months, or something else? If the latter, should the distributor consider the ordering history of all different types of customers—chain pharmacies, independent pharmacies, hospitals, long term care facilities, etc.—or only one or a subset of those customer types? Should the distributor focus on customers within the customer’s own geography? If so, should it look within five miles, 50 miles, or statewide? Once the distributor decides on the appropriate comparators, should it report orders that differ from prior orders by 10%, 100%, or some other threshold? Should it report all orders that differ by a

particular percentage, or can the distributor make different determinations based upon what it knows about a particular customer and its ordering history? With respect to all of these questions and more, distributors are again left to guess.

Thus, while the Government may assert that the statutory definition of a “suspicious order” provides needed clarity, distributors are still left without any standards to guide their determination of whether an order deviates “substantially” from a “normal pattern” or is “unusual” in size or frequency. *See, e.g., McCormack v. Herzog*, 788 F.3d 1017, 1031 (9th Cir. 2015) (definitions of the terms “properly” and “satisfactorily” did not provide clarity because the “definitions raise the same questions as the terms themselves: proper, satisfactory, fit, right, or sufficient according to whom or what standards?”), *abrogated on other grounds, Dobbs v. Jackson Women’s Health Org.*, 142 S. Ct. 2228 (2022); *Hinton v. Devine*, 633 F. Supp. 1023, 1033 (E.D. Pa. 1986) (striking down an executive order because, “in addition to an incomprehensible ‘standard’ which could conceivably be applied differently . . . each time it is invoked,” the order identified certain factors “each of which is itself vague, overbroad, or both”).

This lack of clarity can lead to arbitrary enforcement: Imagine two different distributors. One designs an order monitoring system that flags for further review orders that are three times the size of a pharmacy’s average order. The second distributor designs a system that flags orders for further review that are four times the size of a pharmacy’s average order. Without guidance, it is impossible to determine whether neither, one, or both systems adequately identify potentially suspicious orders based upon the order being an “unusual size.” Indeed, nothing in the statutory and regulatory language would preclude the DEA from claiming, after-the-fact, that *both* systems violate the law because the distributors should have flagged orders that are 2.5

times the size of the average order or that only the second distributor's system fails, because "unusual" meant orders that are three times the size of the average order.

Even more troubling, if the DEA takes the position—as it does here—that distributors must report to the DEA all orders that their own systems flag or else "dispel all suspicion" with regard to those orders (*i.e.*, the proposed regulation that DEA still has not adopted), then the DEA could potentially seek to penalize one—but not both—of the distributors with regard to virtually identical orders. Imagine an order that is 3.5 times the size of a pharmacy's average order. The first distributor's system would flag the order, exposing that distributor to the risk of penalties for failing to report the order to the DEA. However, the second distributor—which did not even flag the order—would not be at risk of a reporting violation (unless the DEA comes up with some other suspicious order theory). This sort of regulatory scheme—whereby one distributor could be penalized for not reporting an order that the second distributor also did not report, with impunity—does not withstand constitutional scrutiny because it fails to tell distributors what conduct violates the law and allows for arbitrary and inconsistent enforcement.

D. The DEA's Failure to Provide Guidance is Further Evidence of Vagueness.

As discussed above, distributors have, for many years, clamored for the DEA to cure these ambiguities by providing guidance regarding their obligation to report suspicious orders. Likewise, various governmental entities have noted the vagueness in the obligations surrounding suspicious orders and repeatedly called on the DEA to fix the problem:

- June 2015 GAO Report at 26, 27, 44, 45 (GAO recommended that the DEA "develop additional guidance for distributors regarding their roles and responsibilities for suspicious order monitoring and reporting" and warned that "without sufficient guidance and communication from DEA, distributors may not be fully understanding and meeting their roles and responsibilities under the CSA" In response, the DEA stated that it "cannot provide more specific suspicious orders guidance");

- June 2016 GAO Testimony at 17 (GAO reiterated the need for the DEA to “provide a guidance document for distributors,” including specific “guidance around best practices in developing suspicious order monitoring systems”);
- September 2019 OIG Report at 31-32 (OIG noted that registrants were applying varying standards regarding suspicious orders and called on the DEA to “establish regulations, policies, and procedures that specifically define what constitutes a suspicious order. . . .”);
- January 2020 GAO Report at 34, 36 (GAO reiterated that “additional guidance from and additional communication with DEA was needed about registrant’s roles and responsibilities” and that specific guidance for distributors relating to suspicious orders “remains relevant and important”); and
- June 2022 GAO Letter (GAO recommended yet again that the DEA “solicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious order monitoring and reporting”).

These numerous industry and governmental inquiries and criticisms of the DEA, all in the public record, provide further evidence—beyond the ambiguity of the statutory and regulatory language itself—that the obligation is unconstitutionally vague. *See, e.g., United States v. Ward*, No. Crim. 00-681, 2001 WL 1160168, *16 (E.D. Pa. Sept. 5, 2001) (“The numerous inquiries directed at OSHA . . . are further evidence that the PSM Regulation is ambiguous and that there was considerable confusion as to its meaning.”).

Now, rather than heeding these calls and fixing the problem, the DEA proposes to insert even more confusion into the regulatory landscape through its invention of a brand new and vague term, “Orders Received Under Suspicious Circumstances,” which the DEA unhelpfully defines as “an order *potentially* meeting the definition of suspicious order.” SOR Notice at 69,298 (emphasis added). The DEA’s proposal is itself evidence that the existing language is insufficient and unclear. Rather than providing clarity, however, the DEA’s proposal would introduce yet an additional layer of confusion. In doing so, the DEA demonstrates the persistent

failure “to establish a standard” that “can provide evidence of vagueness.” *See Johnson*, 576 U.S. at 598 (quoting *Cohen*, 255 U.S. at 91).

* * *

The Government’s Complaint is a prime example of the type of arbitrary enforcement and overreach prohibited by the void for vagueness doctrine. More than ten years after beginning its investigation, and after the DEA approved the registration for every single Defendant distribution center every single year during that period while regularly auditing those facilities, the Government now asserts that the Defendants’ SOMS were improperly designed. It alleges in sweeping fashion that a “huge number of statistically unusual and otherwise suspicious orders” were not flagged for human review. Compl. ¶ 489. But the Government refuses now, as it always has, to explain what makes an order “statistically unusual.” And with regard to orders that were flagged for human review by the Defendants’ SOMS, the Government alleges that “at least hundreds of thousands” of suspicious orders were not reported, but it fails to identify those orders. *Id.* ¶ 446. This type of freewheeling, opaque enforcement is only possible because the suspicious order reporting regime is not “sufficiently explicit to inform those who are subject to it what conduct on their part will render them liable to its penalties.” *Connally*, 269 U.S. at 391. The Complaint should be dismissed.²⁰

²⁰ As discussed above, this Court can consider a host of public records in connection with this Motion. *See supra* n.2. But there is substantial deposition and trial testimony of current and former DEA personnel and other documents further demonstrating that the DEA has failed for many years to provide guidance and that the decision on what constitutes a suspicious order is a subjective one. In the event the Court believes that this additional information would aid it in determining whether the “suspicious order” obligations are unconstitutionally vague, it could defer ruling on this aspect of the Motion and order bifurcated discovery, with the initial phase of discovery focusing on the issue of vagueness. *See Bandai Am. Inc. v. Bally Midway Mfg. Co.*, 775 F.2d 70, 74 (3d Cir. 1985) (bifurcation of discovery “was clearly within the range of the court’s discretion”); *see also United States v. Wright*, 515 F. Supp. 3d 277, 284 (M.D. Pa. 2021) (in context of vagueness challenge to DEA regulation, permitting defendant to file a motion for a

II. THE GOVERNMENT’S COMPLAINT IS PREMISED ON A LEGALLY FLAWED INTERPRETATION OF THE SUSPICIOUS ORDER REPORTING REQUIREMENT.

Under the SUPPORT Act and the SOR Regulation, a distributor’s sole obligations are to design and operate a system to identify suspicious orders, and then to report suspicious orders to the DEA “when discovered.” But, as discussed above, the DEA has refused to provide any guidance to the industry on how to design and operate a SOMS. Instead, it has left it up to each registrant to design its own SOMS. Given this framework, the only way to avoid at least one aspect of the constitutional vagueness problem, as the statute itself makes clear, is to limit a distributor’s reporting obligation to only those orders identified as suspicious orders by its own systems. *See Zadvydas v. Davis*, 533 U.S. 678, 689 (2001) (when a federal statute “raises a serious doubt as to its constitutionality,” a court “will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided”) (internal questions omitted). Otherwise, the Government could seek to impose massive penalties based on its own after-the-fact, *ad hoc* determinations. Here, other than a handful of orders for a few pharmacies, the Government does not allege that Defendants failed to submit reports for orders that their own systems purportedly discovered to be suspicious.²¹ Accordingly, if the Court is unwilling at this time to strike down the suspicious order reporting obligation for vagueness, at a minimum, other than with respect to those few orders, the Complaint should be dismissed.

modified *Daubert* hearing to determine “the question of law of what definition or definitions of ‘positional isomer’ are generally accepted within the scientific community”).

²¹ Defendants dispute these allegations and, if the Complaint is not dismissed, will disprove them at a later stage of the case.

A. The CSA Only Obligates Distributors To Maintain a SOMS and Report Suspicious Orders When Discovered.

The SOR Regulation and SUPPORT Act impose only two requirements on distributors with respect to suspicious order monitoring and reporting. First, a distributor must “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” 21 C.F.R. § 1301.74(b); *see also* 21 U.S.C. § 832(a)(1) (registrant must “design and operate a system to identify suspicious orders for the registrant”). Second, a distributor must “inform” DEA “of suspicious orders *when discovered by the registrant.*” 21 C.F.R. § 1301.74(b) (emphasis added); *see also* 21 U.S.C. § 832(a)(3) (requiring distributor to notify DEA only “*upon discovering* a suspicious order or series of orders”) (emphasis added).

With respect to the first requirement, neither the statute, the regulations, nor the DEA dictates or even provides guidance as to how such a system shall be “design[ed] and operate[d].” Instead, the DEA has long taken the position that registrants have wide latitude in the design and operation of their SOMS; there is, according to the DEA, no one-size-fits-all approach; and the DEA has stated that it will play no role in requiring or even suggesting any particular design. *See supra* 9-15, 26-28. While the DEA leaves it to registrants to design their systems, it provides a crucial oversight role. As discussed above, the DEA conducts periodic compliance inspections covering order monitoring systems and has broad authority to take action with respect to deficient systems, including suspending or revoking a registration. 21 U.S.C. §§ 822(f), 824(a)(4). It also decides whether to renew a distributor’s registration each year. *Id.* § 822(a)(1).

With respect to the second requirement, registrants must report suspicious orders only “*when discovered*” by their varied, self-designed order monitoring systems. 21 C.F.R. § 1301.74(b); *see also* 21 U.S.C. § 832(a)(3) (requiring reporting “*upon discovering*”). This regime leads to a single, inescapable conclusion: a distributor is not required to report an order

as suspicious if its order monitoring system does not identify an order as suspicious. That does not provide the distributor with free rein; if it does not have a satisfactory system, the DEA has the ability to suspend, revoke, or disapprove its registration or make adverse audit findings. But the Government does not have the authority to bring a case like this one.

B. The Government Fails to State a Claim With Regard to Unflagged Orders that Defendants' SOMS did not Discover.

Here, the Complaint makes clear that Defendants had order monitoring systems. *See, e.g.*, Compl. ¶¶ 102, 150, 197. The Government does not allege that the DEA ever made any adverse findings regarding those systems during any of its audits of Defendants' dozens of distribution facilities. Nor does the Government allege that the DEA ever suspended, revoked, or refused to renew any of Defendants' numerous registrations, or attempted to do so. Nevertheless, the Government seeks penalties for Defendants' alleged failure to report orders that their systems did not even flag for further review. *Id.* ¶ 486. But these orders by definition were not "discovered" to be suspicious by Defendants. Thus, the Government fails to state a claim for penalties under Section 842(a)(5) with respect to these orders.

A distributor can only face liability under the CSA for failing to report suspicious orders that it discovers. *See* 21 U.S.C. § 832(a)(3) (imposing reporting requirements "upon discovering a suspicious order"); 21 C.F.R. § 1301.74(b) (requiring registrants to inform DEA "of suspicious orders when discovered"). That is not only apparent based on the plain text of the CSA and its regulations, but it is also a logical conclusion based on the statutory scheme's design. If the reporting duty applied to all orders that could theoretically be deemed suspicious by *any* monitoring system, whether actually discovered by the distributor or not, there would be no need to impose a separate and independent duty to design and operate a monitoring system.

If the DEA believes a distributor has not maintained “effective controls,” the remedy is an enforcement action to revoke the distributor’s license. 21 U.S.C. §§ 823(a)(1), 824(a)(4). The DEA could also issue negative findings during one of its audits. But despite conducting dozens of audits and having the opportunity every year not to renew Defendants’ registrations, the DEA never took that kind of action during the time period at issue.

The Government’s attempt to impose liability through this category of conduct is even more problematic given the DEA’s refusal, for over a decade, to provide any instructions regarding how to design a SOMS, including how to set thresholds for flagging orders, appropriate levels at which those thresholds should be set, or how those thresholds should be implemented. *See supra* 9-15, 26-27. Defendants designed systems they believed would identify suspicious orders. Any orders that may not have been identified by the operations of those systems did not need to be reported because Defendants never “discovered” them. Thus, this category of violations fails.

C. Even With Respect to Flagged Orders, The Government Fails to State a Claim With Respect to Orders That Defendants Did Not Discover to be Suspicious.

The Government also alleges that Defendants were obligated to report to the DEA hundreds of thousands of unidentified orders that the computerized portion of their SOMS had flagged for further review, but that Defendants’ human reviewers ultimately did not determine to be suspicious. Specifically, the Government alleges that these flagged orders were presumptively suspicious and should have been reported to the DEA because Defendants did not dispel suspicion with regard to them. *E.g.*, Compl. ¶¶ 10, 53-55, 208-12, 272, 443, 447. The Government’s theory fails on its face for two separate reasons: first, it misapplies *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017); and, second, it relies on

recordkeeping duties that do not exist under federal law and that would in any event violate the Paperwork Reduction Act.

1. The Government Misapplies Masters.

An order is not suspicious merely because a distributor's computer system flags it for further review. The government pins its contrary interpretation on the D.C. Circuit's decision in *Masters*, but that case does not support the Government's interpretation of the reporting obligation.

Masters involved a petition for review of the DEA's determination to revoke a distributor's license after the distributor failed to report orders that its own system identified as suspicious. Unlike the two-step framework that defines Defendants' monitoring system, which flags orders of interest in the first instance for subsequent human review, Masters' computer system was designed, pursuant to Masters' own policies, to flag suspicious orders for which any suspicion then had to be dispelled. *Id.* at 216. Thus, if Masters did not dispel suspicion for those orders, it failed to report orders that its system disclosed as suspicious to the distributor.

Nowhere in *Masters* did the government argue or did the court rule that the *Masters* system is the model that all other registrants must follow. To the contrary, the government disclaimed that very position. In its brief to the D.C. Circuit, the government recognized that, while "the Administrator's decision highlighted Masters' failure to follow its own compliance policies, *it did not impose those policies on other distributors.*" Respondent's Br. at 14, Dkt. 1612884, *Masters Pharm. Inc. v. DEA*, No. 15-1335 (D.C. Cir.) (emphasis added); *see id.* at 36-37 ("[I]n highlighting Masters' disregard for its own program's requirements, the Administrator did not impose those same requirements on all registered distributors.").

Given the Government's admissions that the *Masters* framework does not apply to all distributors and the DEA's direction that distributors should design their systems as they see fit,

the Government cannot reverse course and ignore how Defendants' systems actually work. Addressing this very issue, the West Virginia federal court correctly concluded that the D.C. Circuit "did not purport to mandate [the Masters] SOM program for other distributors" and that the plaintiffs' expert in that case erred by failing "to judge defendants' conduct against their own SOMS." *Huntington*, 609 F. Supp. 3d at 442. The Complaint makes the same mistake here. Under Defendants' systems, an order is not suspicious unless it is determined to be suspicious by human reviewers. Thus, there is no suspicion to "dispel" with respect to the orders of interest flagged by the computer algorithm.

2. The Government's Theory Relies on Recordkeeping Duties That Do Not Exist.

The Government's "report or dispel" theory also fails as a matter of law because it is premised on recordkeeping requirements not present in federal law. The Government improperly attempts to use an alleged *lack of documentation*—years after the fact—to claim that Defendants failed to dispel suspicion with respect to "at least hundreds of thousands of orders." *E.g.*, Compl. ¶¶ 446, 447, 449, 459, 473. But federal law has never imposed recordkeeping duties related to suspicious order reporting. *See Huntington*, 609 F. Supp. 3d at 444.

The DEA's SOR Notice recognizes that the proposed amendments to the SOR Regulation include "new requirements" for "recordkeeping." SOR Notice at 69,291. For the first time, the newly proposed rule would "require[] registrants to maintain a record of every suspicious order and every [order received under suspicious circumstances], and how the registrant handled such orders." *Id.* at 69,292. And, for the first time, the proposed rule would specify what information those records "must include," such as "[w]hat steps, if any, the registrant took to conduct due diligence" and the "specific basis" for concluding that "each suspicious circumstance has been dispelled." *Id.* Under the proposed amendments, distributors would be required to keep such

records for two years. *Id.* at 69,293. Of course, it bears noting again that these “new requirements” have not yet been adopted.

Even if the SOR Notice had been adopted, the Government’s attempt to impose these proposed new requirements on a retroactive basis would be a nonstarter, as that would plainly exceed any rulemaking authority it has under the CSA. *See, e.g., Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212-213 (1988) (striking down agency’s attempt to impose rule on retroactive basis). Moreover, the Government here seeks to reach back nine years, when the proposed new rule would require such records to be kept for only two years. Worst of all, the Government uses these unadopted new requirements to demand billions of dollars.

3. The Government’s Theory Violates the Paperwork Reduction Act.

Even if the DEA had implicitly imposed a requirement on distributors to keep records to later justify their handling of particular orders, that would not save the Government’s claim because the DEA never obtained approval for such a recordkeeping requirement under the Paperwork Reduction Act.

Congress enacted the PRA to “minimize the paperwork burden” on “persons resulting from the collection of information by or for the Federal Government.” 44 U.S.C. § 3501(1). “In striking the balance between minimizing the burden on the public and obtaining useful information for the government, Congress established a procedure in which federal agencies must obtain approval from the Office of Management and Budget (‘OMB’) to collect certain types of information from the public.” *Nat’l Women’s Law Ctr. v. Off. of Mgmt. & Budget*, 358 F. Supp. 3d 66, 71 (D.D.C. 2019).

To comply with the PRA, an agency proposing a “collection of information” must first seek OMB’s approval, justifying the proposed collection. 44 U.S.C. §§ 3506(c), 3507(a). An agency may not engage in a collection of information unless the OMB has approved of the

collection and issued a control number, which must be displayed on the collection of information. *Id.* § 3507(a)(2), (3); 5 C.F.R. § 1320.12(e). Agencies must obtain such approval every three years. 44 U.S.C. § 3507(g); 5 C.F.R. § 1320.12(e).

The term “[c]ollection of information” includes “identical reporting or recordkeeping requirements imposed on . . . ten or more persons.” 44 U.S.C. § 3502(3); *see also* 5 C.F.R. § 1320.3(c). A collection can be “direct” or “indirect.” *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 33 (1990). Direct collections are traditional reporting requirements, whereas “indirect” collections refer to recordkeeping burdens. *Id.* at 33 n.4; 5 C.F.R. § 1320.3(c), (c)(1), (m).

If an agency fails to comply with these requirements, the PRA provides a “complete defense” for alleged violations of reporting and recordkeeping obligations. The public protection provision of the PRA (“Public Protection Provision”) states in part:

(a) Notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information . . . if . . . the collection of information does not display a valid control number assigned by the Director in accordance with this subchapter.

* * *

(b) The protection provided by this section may be raised in the form of a complete defense, bar, or otherwise at any time

44 U.S.C. § 3512. The upshot of the Public Protection Provision is that “the public may ignore [any unapproved collection requirement] without risk of penalty.” *Dole*, 494 U.S. at 40. As the DEA itself recognizes, the “DEA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number.” SOR Notice at 69,297.

Here, any obligation for Defendants to document how they “dispelled suspicion” with regard to flagged orders would constitute a “collection of information” under the PRA. 44 U.S.C. § 3502(a)(3)(A)(i) (defining a “collection of information” to include “reporting

or recordkeeping requirements imposed on . . . ten or more persons”); *see also* 5 C.F.R. §1320.3(c)(4)(i), (ii) (collections of information contained within a “rule of general applicability” or addressed to “all or a substantial majority of an industry” are presumed to satisfy the ten person requirement). Indeed, as discussed above, the DEA has proposed (but not adopted) a new regulation that would include these very sorts of documentation requirements. And the DEA has conceded that, if approved, these recordkeeping requirements would constitute a “new” collection of information. DEA Supp. Stmt., Ex. 2 at 4; SOR Notice at 69,297.

Moreover, the DEA has never obtained OMB approval for any such collection of information. Governmental websites listing approved collections of information do not identify any DEA collections of information regarding suspicious order monitoring for controlled substances. View Information Collection Request (ICR) Package, ICR Ref. No. 202012-1117-001 (Ex. 3) (identifying “0” prior approvals).

Because the DEA did not receive OMB approval to impose recordkeeping obligations related to suspicious orders, under the Public Protection Provision, the Government is legally barred from pursing its failure to dispel suspicion theory predicated on an alleged lack of documentation. *See* 44 U.S.C. § 3512(a); *see also* *United States v. Hatch*, 919 F.2d 1394, 1396–98 (9th Cir. 1990) (reversing criminal conviction based on Forest Service regulation because “[agency] did not comply with the PRA,” meaning defendant “cannot be subject to any penalty”); *United States v. Smith*, 866 F.2d 1092, 1098–99 (9th Cir. 1989) (reversing criminal conviction because agency violated PRA). Accordingly, for this additional reason, the Government’s “report or dispel” legal theory fails.

D. Defendants Had No Blanket Requirement To Report All Orders Placed By Purportedly “Suspicious Customers.”

The Government takes the position that certain orders are necessarily suspicious because the “customer placing the order was potentially facilitating the diversion of controlled substances.” Compl. ¶ 274. But under the CSA and implementing regulations, there is no such thing as a “suspicious customer.” Instead, the reporting requirement operates at the individual “order” level. 21 U.S.C. § 832(a); 21 C.F.R. § 1301.74(b).

In light of the statute, the Government must prove liability on an order-by-order basis. It cannot shortcut this obligation by asserting that every order placed by a customer with purported “red flags” is automatically suspicious without regard to the specific facts of any particular order. For this reason, in the West Virginia case, the court rejected the plaintiffs’ expert’s analysis that “employ[ed] an assumption that once an order is flagged, all future orders are permanently and automatically to be flagged as suspicious as well.” *Huntington*, 609 F. Supp. 3d at 441-442. The court found that this assumption led to “an entirely unpersuasive result.” *Id.* at 448.

The Government makes that same error here. The crux of its theory is that once a customer has done anything that could arguably be deemed suspicious, every order from that customer from that point forward must be reported and not shipped. This is tantamount to having to terminate the customer. This approach is not faithful to the statute, which looks at the circumstances of individual orders, and would also threaten patient access to needed medications. Indeed, even pharmacies with purported red flags fill many legitimate prescriptions. If the DEA truly believed that a pharmacy should not be dispensing any controlled substances, it—and it alone—has the power to stop the pharmacy from doing so by revoking the pharmacy’s registration. Accordingly, to the extent that the Complaint relies on Defendants’

failure to report orders based solely upon their having been placed by purportedly “suspicious customers,” it should be dismissed.

E. The Government’s Allegations Otherwise Fail To Comply with Rule 8.

Beyond failing to state a claim regarding orders that Defendants did not discover to be suspicious, the Government also fails to plead sufficient facts even to satisfy Federal Rule of Civil Procedure 8. The Supreme Court has held that a complaint must “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). As the Third Circuit has noted, “context matters in notice pleading.” *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 232 (3d Cir. 2008). Here, the context screams out for the Government to do more than describe the alleged suspicious orders using generalizations regarding broad categories: the Government will have to prove its claim on an order-by-order basis; the obligations at issue are vague; Defendants filled tens of millions of orders per year; the Government investigated for over a decade; and the Government now claims “at least hundreds of thousands” of violations occurring over nine years during which it was actively investigating these issues and while it continued to renew Defendants’ licenses and issued no adverse inspection findings. Under these circumstances, fair notice under Rule 8 requires the Government to do more.

The Government claims that Defendants committed a separate CSA violation with respect to each individual order they allegedly failed to report. Compl. ¶¶ 484-85. Accordingly, the Government has the burden to prove its claim on an order-by-order basis. *See, e.g., United States v. Tran Trong Cuong*, 18 F.3d 1132, 1141-42 (4th Cir. 1994) (reversing conviction of 80 CSA violations because government’s theory invited the “jury to find guilt by association or as a result of a pattern” rather than offering evidence as to each prescription); *United States v. Brizuela*, 962 F.3d 784, 797 (4th Cir. 2020) (because violation of § 841 of CSA is “prescription

specific, and writing a prescription only violates § 841 if, in doing so, the doctor strays from bounds of professional medical practices *in treating that specific patient*,” government must show “whether in writing the cited prescription, the defendant doctor was treating *the patient receiving the prescription* within the bounds of professional medical practices”) (emphasis in original); *Huntington*, 609 F. Supp. 3d at 438, 442 (rejecting attempt to prove violations of suspicious order reporting regulation through aggregate proof and criticizing expert’s testimony as “unpersuasive” for failing “actually [to] review any of the orders”).

Defendants have no way of ferreting out what orders are at issue. As shown above, the suspicious order obligations are themselves vague, and the DEA has refused to provide clarity as to what is required. Instead, the DEA has taken the position that “it cannot provide more specific suspicious orders guidance because the variables that indicate a suspicious order differ among distributors and their customers.” June 2015 GAO Report at 45. Just as there is no way for distributors to determine in advance whether the DEA would consider an order to be suspicious, Defendants can only guess about which orders the Government now claims in hindsight were suspicious, and why.

The Complaint provides no help. Defendants fill tens of millions of orders for controlled substances every year. Compl. ¶ 74. But instead of identifying specific violations, the Complaint is riddled with imprecise and vague allegations. *See, e.g., id.* ¶ 274 (“on numerous occasions”); ¶ 432 (“numerous occasions”); ¶ 443 (“at least hundreds of thousands of occasions”); ¶ 449 (“tens of thousands of instances”); ¶ 458 (“many thousands of analogous orders”); ¶ 459 (“over one hundred thousand instances”); ¶ 472 (“many thousands of analogous orders”); ¶ 473 (“tens of thousands of additional instances”); ¶ 489 (“a huge number of” orders).

Other than with respect to a handful orders for a few pharmacies,²² the Government pleads no facts putting Defendants on notice of which orders are purportedly suspicious and why. This is not a situation in which the Government is unable to plead the bases for its claims. To the contrary, the Government investigated for over a decade and has all the facts—set forth in voluminous documents produced at the Government’s behest—in its possession. Nor is this a situation where the Government can avoid pleading these facts because the purported violations all flow from common conduct. Rather, the government is challenging thousands of individual decisions by different compliance personnel reviewing different orders, placed by different customers, in different places, for different products, in different amounts, at different times. If that were not enough, the Government alleges that Defendants not only failed to report unspecified flagged orders, but also failed to report a “huge number” of unidentified additional orders that Defendants’ systems did not even flag for review. Compl. ¶ 489. There is no way for Defendants to identify these orders out of the tens of millions of orders each year.

Given the circumstances described above, the Government should be required to provide additional detail regarding the orders at issue. *See Kemezis v. Matthew*, No. 07-5086, 2008 WL 5191587, at *3 (E.D. Pa. Dec. 10, 2008) (dismissing claims that included “no factual allegations

²² In the Complaint, the Government makes a handful of allegations regarding nine pharmacies, identified as Pharmacy 1 through Pharmacy 9. The Government’s theory of liability with respect to these nine pharmacies will be disproven at a later stage of this litigation. For purposes of this Motion, however, Defendants do not seek dismissal of the allegations regarding particular orders from these nine pharmacies based upon either the Government’s failure to allege that Defendants discovered the orders to be suspicious or failure to plead in conformity with Rule 8. Defendants do seek dismissal of these allegations for the other reasons set forth in this Motion: (1) because they are based upon Defendants’ alleged violation of unconstitutionally vague obligations; and (2) because recovery is not available with respect to conduct arising pre-SUPPORT Act and to the extent that the DEA failed to comply with the Paperwork Reduction Act. Defendants also seek dismissal of allegations regarding these nine pharmacies to the extent they are based on sweeping allegations that do not identify specific orders.

[in] support” because “without some factual allegation in a complaint a claimant cannot satisfy the requirement that he or she provide not only ‘fair notice,’ but also the ‘grounds’ on which the claim rests”) (quoting *Phillips*, 515 F.3d at 232)); *Residential Funding Co., LLC v. Embrace Home Loans*, 27 F. Supp. 3d 980, 985 (D. Minn. 2014) (dismissing complaint under Rule 8 because the plaintiff “should have pled the specific defects in [the disputed] loans rather than merely a laundry list of defects that may or may not appear in any of [defendant’s] loans”).

III. THE COMPLAINT FAILS TO STATE A CLAIM FOR CONDUCT OCCURRING BEFORE OCTOBER 24, 2018.

For two additional reasons, the Complaint fails to state a claim for suspicious order reporting violations before October 24, 2018, when Congress enacted the SUPPORT Act. First, the CSA allows the Government to recover penalties only for violations of suspicious order reporting obligations that appear in the CSA itself—not for the violation of DEA regulations. But until the enactment of the SUPPORT Act, the statute contained no such reporting obligation. Second, even if a violation of the SOR Regulation could give rise to penalties, the Public Protection Provision provides a “complete defense” because the DEA failed to obtain approval under the Paperwork Reduction Act for the reporting requirement.

A. Because Section 842(a)(5) Penalizes Only Violations of the CSA Itself, the Government Fails to State a Claim for Violations of the SOR Regulation.

The Government seeks penalties for alleged violations of a CSA provision that prohibits failing “to make . . . any report . . . required *under this subchapter.*” 21 U.S.C. § 842(a)(5) (emphasis added). However, until the passage of the SUPPORT Act, no provision of the CSA itself obligated registrants to report suspicious orders to the DEA. Instead, the suspicious order reporting obligation appeared solely in the SOR Regulation, 21 C.F.R. § 1301.74(b). Because Congress authorized penalties for violations of only statutory—as opposed to regulatory—reporting duties, the Government’s pre-SUPPORT Act allegations fail.

1. Supreme Court and Third Circuit Precedent Prohibits the Imposition of Penalties Based Upon the SOR Regulation.

Supreme Court and Third Circuit precedent make clear that “this subchapter” means what it says: the statute itself. In *Kucana v. Holder*, the Supreme Court addressed whether a provision of the Immigration and Nationality Act (the “INA”) prohibiting judicial review of administrative actions “specified *under this subchapter* to be in the discretion of the Attorney General,” also applied to a decision made discretionary by regulation. 558 U.S. 233, 237 (2010) (quoting 8 U.S.C. § 1252(a)(2)(B)(ii) (emphasis added)). The lower court dismissed the appeal, believing that the statutory bar on judicial review was broad enough to encompass discretion specified by regulation. *Id.* at 240. The Supreme Court rejected this expansive reading, holding instead that the “key words ‘specified under this subchapter’” referred only to “statutory, but not to regulatory, specifications.” *Id.* at 237.

The Court grounded its decision in “statutory context,” including that Congress referred to the “Act, or the regulations issued thereunder” in other INA provisions. As such, if Congress wanted the jurisdictional bar to encompass decisions specified as discretionary by regulation, and not just by statute, it “could easily have said so.” *Id.* at 248. This reading was also corroborated by legislative history, including that Congress later amended the INA without disturbing prior case law narrowly construing the jurisdictional bar. *Id.* at 249-51.

Even before *Kucana*, the Third Circuit held that a statute imposing penalties for violations of “this subchapter” excluded regulatory violations. See *Groves v. Modified Ret. Plan for Hourly Paid Emps. of Johns Manville Corp. & Subs.*, 803 F.2d 109 (3d Cir. 1986). There, the court construed Section 502(c) of the Employee Retirement Income Security Act (“ERISA”), which authorizes penalties against a plan administrator for failing “to comply with a request for any information which such administrator is required by *this subchapter* to furnish to a

participant or beneficiary” *Id.* at 114 (quoting 29 U.S.C. § 1132(c)) (emphasis added). The district court found, and the Third Circuit agreed, that the plan administrator violated an ERISA regulation by furnishing a deficient benefits notice. *Id.* at 114.

Despite finding a regulatory violation, the Third Circuit held that Section 502(c) penalties were unavailable because “the words ‘this subchapter’ . . . refer[] only to violations of statutorily imposed obligations, and . . . do[] not embrace violations of regulations promulgated pursuant to the statute.” *Id.* at 111. While noting that the language “this subchapter” could “arguably” include “both the provisions of ERISA itself and the regulations promulgated pursuant to that statute,” the Third Circuit rejected that expansive reading for two reasons. *First*, the Supreme Court “long ago” rejected this view, holding instead “that Congress will be understood to have authorized agencies to decide what conduct should be penalized only if the legislature has expressly granted that power” in “plain[]” and “unmistakabl[e]” terms. *Id.* at 117-18. *Second*, a narrow approach was “impelled by the rule of lenity,” to ensure “sanctions are not imposed” without “‘fair warning.’” *Id.* at 118 (quoting *Huddleston v. United States*, 415 U.S. 814, 831 (1974)).

Groves broke no new ground. More than 130 years ago, the Supreme Court held that if Congress intends to penalize regulatory violations, it must do so “distinctly” in the statute. *United States v. Eaton*, 144 U.S. 677, 688 (1892). In *Eaton*, the Court held that a wholesaler’s failure to comply with a regulation to keep records did not violate a statute penalizing failure to do anything “required by law” where the statute did not refer expressly to the regulation. *Id.* In contrast, the Supreme Court later held that regulatory violations were punishable where Congress “distinctly” expressed that intent in the statute by providing that “any violation of the provisions

of this act *or such rules and regulations* [of the Secretary of Agriculture] shall be punished.”

United States v. Pierre Grimaud, 220 U.S. 506, 515, 519 (1911).

Congress is presumed to “legislate with knowledge of [the Supreme Court’s] basic rules of statutory construction,” *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 496 (1991), and “relevant judicial precedent,” *Ryan v. Gonzales*, 568 U.S. 57, 66 (2013) (citation omitted). In the 130 years since *Eaton*, Congress has enacted many laws that “distinctly” penalize regulatory violations. *See, e.g.*, 43 U.S.C. § 1350(c) (Outer Continental Shelf Lands Act authorizing penalties for anyone who “violates any provision of this subchapter . . . or any regulation or order issued under the authority of this subchapter”) (emphasis added); 33 U.S.C. § 1415(a) (Marine Protection, Research, and Sanctuaries Act providing that violators of “any provision of this subchapter, or of the regulations promulgated under this subchapter . . . shall be liable”) (emphasis added). *Accord* 7 U.S.C. § 2024(b)(1) (same for Supplemental Nutrition Assistance Program); 16 U.S.C. § 668dd(f)(1) (same for National Wildlife Refuge System); 16 U.S.C. § 703(a) (same for Migratory Bird Treaty Act); 49 U.S.C. § 30165(a)(1) (same for Motor Vehicle Safety Act). But Section 842(a)(5) of the CSA is not one of them.

2. Other Provisions of the CSA, Statutory History, and the Rule of Lenity Further Undermine The Government’s Reliance on the SOR Regulation.

Here, as in *Kucana* and *Groves*, the plain meaning of the term “this subchapter” encompasses the statute itself and not any regulation related to the Act. Thus, as in *Groves*, the plain language of the statute “precludes the imposition of sanctions for violation of agency regulations.” *Groves*, 803 F.2d at 117. This conclusion is further compelled by the same considerations underlying *Kucana* and *Groves*.

As in *Kucana*, the fact that Congress referred to regulations elsewhere in the CSA, but not in Section 842(a)(5), is powerful evidence that “this subchapter” means the statute itself.

Unlike Section 842(a)(5), another subsection of section 842(a) itself expressly prohibits the failure to comply with regulations. *See* 21 U.S.C. § 842(a)(14) (prohibiting registered sellers from disclosing “in violation of regulations under subparagraph (c) of section 830(e)(1) of this title” certain information or from refusing to provide such information to law enforcement authorities). Given Section 842(a)(14)’s express reference to regulations, Section 842(a)(5)’s failure to refer to regulations is particularly significant. As this Court has explained, “[w]hen one section of a statute contains a particular provision, the ‘omission of the same provision from a similar section is significant to show’ a difference in meaning between the two sections.”

Giovanni v. U.S. Dep’t of the Navy, 433 F. Supp. 3d 736, 745 (E.D. Pa. 2020) (Pappert, J.) (quoting 2A N. Singer, *Sutherland on Statutory Construction* § 46.07 (6th ed. 2000)).

In various other CSA sections, Congress likewise expressly referenced the statute and regulations. *See, e.g.*, 21 U.S.C. § 828(a) (“in accordance with subsection (d) and regulations”); *id.* § 829(f)(1)(B) (“in accordance with this subchapter, regulations prescribed by the Attorney General, and State law”); *id.* § 880(d)(1) (“enforcement of this subchapter or regulations thereunder”). By prohibiting the failure to make reports “required under *this subchapter*,” while expressly referencing regulatory requirements elsewhere in the statute, however, Congress signaled that Section 842(a)(5) did not itself encompass requirements imposed only by regulation. *See, e.g., Nken v. Holder*, 556 U.S. 418, 430 (2009) (“[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”); *Giovanni*, 433 F. Supp. 3d at 745.

The history of the CSA’s amendments likewise confirms that Section 842(a)(5) does not apply to the SOR Regulation. When Congress passed the SUPPORT Act in October 2018, it

amended the CSA by importing a nearly verbatim version of the SOR Regulation into Subchapter I, 21 U.S.C. § 832, and separately adding penalties for violating the new provision, *id.* § 842(c)(1)(B)(ii). “When Congress amends legislation, courts must presume it intends the change to have real and substantial effect,” *Van Buren v. United States*, 141 S. Ct. 1648, 1660 (2021) (citation omitted). Had civil penalties already been available for violating the SOR Regulation, these amendments would have had no purpose or effect.

Finally, as in *Kucana*, any “lingering doubt” is “dispelled” by a “familiar principle of statutory construction.” 558 U.S. at 251. That principle, as the Third Circuit made clear in *Groves*, is the rule of lenity. 803 F.2d at 118-19. Section 842(a)(5) authorizes severe civil and criminal penalties. *See* 21 U.S.C. §§ 842(a)(5), (c)(2)(A). As such, it is plainly a penal statute that, under the rule of lenity, should be “construed narrowly, so that sanctions are not imposed.” *Groves*, 803 F.2d at 118. Indeed, ““the law is settled”” that a private party ““is not to be subjected to a penalty unless the words of the statute plainly impose it.”” *Bittner v. United States*, 143 S. Ct. 713, 724 (2023) (applying rule of lenity to construe Bank Secrecy Act reporting provision narrowly); *see also Burrage v. United States*, 571 U.S. 204, 216-17 (2014) (applying rule of lenity to CSA and explaining that the Court could not adopt an interpretation that “disfavors the defendant”); *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004) (holding that where a statute “has both criminal and noncriminal applications,” courts should interpret the statute consistently in both criminal and noncriminal contexts, and “the rule of lenity applies”); *Cleveland v. United States*, 531 U.S. 12, 25 (2000) (when interpreting penal statute “it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite”); *Bergamatto v. Bd. of Tr. of the NYSA-ILA Pension Fund*, 933 F.3d 257, 268 (3d Cir. 2019) (“[P]enal provision[s] . . . should be leniently

and narrowly construed[.]”). In *Groves*, the Third Circuit was “impelled by the rule of lenity” to construe a penal provision referring to “this subchapter” to apply “only to violations of statutorily imposed obligations,” 803 F.2d at 111, 118. The same is true here.

B. The DEA’s Failure to Comply with the Paperwork Reduction Act Immunizes Defendants From Any Penalties.

The Government’s pre-SUPPORT Act allegations are also barred because the DEA has never complied with the Paperwork Reduction Act with respect to suspicious order reporting. As discussed above, this failure affords Defendants a “complete defense” as a matter of law. 44 U.S.C. § 3512(b).

Prior to the enactment of the SUPPORT Act, the obligation to report suspicious orders arose solely under the SOR Regulation. However, the DEA never obtained OMB approval for that reporting requirement. As such, under the Public Protection Provision, Defendants have a complete defense to any claim based upon their alleged failure to report suspicious orders under the SOR Regulation. *See supra* 35-37.²³

CONCLUSION

Defendants have complied with their obligations to design and operate a system to detect and report suspicious orders. In claiming otherwise, the Government contorts an unconstitutionally vague suspicious order reporting regime to demand exorbitant penalties for “at least hundreds of thousands” of supposed violations that the Government still refuses to identify

²³ This PRA defense applies to the obligation to report suspicious orders prior to the enactment of the SUPPORT Act. As such, it is distinct from the PRA defense described above, which applies to the Government’s attempt to recover based upon Defendants’ alleged failure to comply with an unapproved recordkeeping obligation both pre- and post-SUPPORT Act. *See* View Information Collection Request (ICR) Package, ICR Ref. No. 202012-1117-001 (Ex. 3) (DEA’s December 2020 request for approval for a new “collection of information” that “would include two distinct components: the reporting of suspicious orders, and recordkeeping related to suspicious orders and ORUSCs”).

for Defendants even after its decade-long investigation. The Government's lawsuit is not only an unfair overreach, but it also fails as a matter of law. Accordingly, the Court should dismiss the Complaint in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2023, I served a true and correct copy of the foregoing upon all counsel of record via the Court's CM/ECF electronic filing system.

/s/ Andrew J. Levander

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